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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/775,973 | 02/09/2004 | Lawrence W. Stanton | 219002031710 | 1838 |
| 25225 7590 07/30/2007 MORRISON & FOERSTER LLP 12531 HIGH BLUFF DRIVE SUITE 100 SAN DIEGO, CA 92130-2040 | | | EXAMINER SITTON, JEHANNE SOUAYA | |
| | | | ART UNIT 1634 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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| <div style="border: 1px solid black; width: 200px; height: 20px; margin-bottom: 10px;"></div> <p style="text-align: center;">Office Action Summary</p> | <p>Application No.</p> <p style="text-align: center;">10/775,973</p> | <p>Applicant(s)</p> <p style="text-align: center;">STANTON ET AL.</p> | |
| | <p>Examiner</p> <p style="text-align: center;">Jehanne S. Sittón</p> | <p>Art Unit</p> <p style="text-align: center;">1634</p> | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3 and 5-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3, 5-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| <p>1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application</p> <p>6) <input type="checkbox"/> Other: _____.</p> |
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DETAILED ACTION

Election/Restrictions

1. Currently, claims 3 and 5-9 are pending in the instant application. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. The following rejections are either newly applied, as necessitated by amendment, or are reiterated. They constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow. This action is FINAL.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The rejections made at sections 6, 8, 10, and 11 of the previous office action are withdrawn in view of the amendments to the claims.

Claim Rejections - 35 USC § 101

4. Claims 3 and 5-9 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

Definitions: [from REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS; repeated from <http://www.uspto.gov/web/menu/utility.pdf>]

"Credible Utility" - Where an applicant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by Office personnel as being "wrong". Rather, Office personnel must determine if the assertion of utility is credible (i.e., whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided). An assertion is credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based is inconsistent with the logic underlying the assertion. Credibility as used in this context refers to the reliability of the statement based on the logic and facts that are offered by the applicant to support the assertion of utility. A credible utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use. For example, no perpetual motion machines would be considered to be currently available. However, nucleic acids could be used as probes, chromosome markers, or forensic or diagnostic markers. Therefore, the credibility of such an assertion would not be questioned, although such a use might fail the specific and substantial tests (see below).

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"Specific Utility" - A utility that is specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention. For example, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be specific in the absence of a disclosure of a specific DNA target. Similarly, a general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed.

"Substantial utility" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring. On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

A. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved.

B. A method of treating an unspecified disease or condition. (Note, this is in contrast to the general rule that treatments of specific diseases or conditions meet the criteria of 35 U.S.C. ' 101.)

C. A Method of assaying for or identifying a material that itself has no "specific and/or substantial utility."

D. A method of making a material that itself has no specific, substantial, and credible utility.

E. A claim to an intermediate product for use in making a final product that has no specific, substantial, and credible utility.

Note that "throw away" utilities do not meet the tests for a specific or substantial utility. For example, using transgenic mice as snake food is a utility that is neither specific (all mice could function as snake food) nor substantial (using a mouse costing tens of thousands of dollars to produce as snake food is not a "real world" context of use). Similarly, use of any protein as an animal food supplement or a shampoo ingredient are "throw away" utilities that would not pass muster as specific or substantial utilities under 35 U.S.C. ' 101. This analysis should, or course, be tempered by consideration of the context and nature of the invention. For example, if a transgenic mouse was generated with the specific provision of an enhanced nutrient profile, and disclosed for use as an animal food, then the test for specific and substantial asserted utility would be considered to be met.

A "Well established utility" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. "Well established utility" does not encompass any "throw away" utility that one can dream up for an invention or a nonspecific utility that would apply to virtually every member of a general class of materials, such as proteins or DNA. If this is the case, any product or apparatus, including perpetual motion machines, would have a "well established utility" as landfill, an amusement device, a toy, or a paper weight; any carbon containing molecule would have a "well established utility" as a fuel since it can be burned; any protein would have well established utility as a protein supplement for animal food. This is not the intention of the statute.

See also the MPEP at 2107 - 2107.02.

The claimed nucleic acids are not supported by a specific asserted utility because the disclosed uses of the nucleic acids are not specific and are generally applicable to any nucleic acid. The specification teaches that the invention is based on the identification of a gene that is differentially expressed in the left ventricle of the rat Myocardial infarction model, in the rat

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Cardiac Hypertrophy Model, and in the mouse Viral Myocarditis model (p. 20, lines 9-11).

Claim 3 is directed to an array which comprises any oligonucleotide which is complementary to a "reference" RNA or DNA encoding SEQ ID NO: 1 or a mammalian homologue thereof, wherein the reference DNA or RNA is obtained from both a biological sample taken from a normal subject and a biological sample taken from a subject exhibiting a cardiac, renal or inflammatory disease or from a biological sample taken at different stages of a cardiac, renal or inflammatory disease. The specification asserts that the nucleic acids of the invention, and particularly SEQ ID NO 2 can be used to design specific probes and primers, can be used in detection, diagnostic, prognostic methods, vector constructs, antibody constructs, etc (p. 42-48). However, these are non-specific uses that are applicable to nucleic acids in general and not particular or specific to the nucleic acid being claimed.

Further, the claimed nucleic acids are not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. The specification states that when characterization of the differentially expressed genes indicate that modulation of the gene's expression or the gene product's activity can inhibit or treat a disease, specifically cardiac, kidney, or inflammatory diseases, the differentially expressed gene or its gene product becomes a potential drug candidate or a target for developing a drug candidate for the treatment of a cardiac, kidney or inflammatory disease, or may be used as a diagnostic. However, the specification has not taught the activity of the polypeptide of SEQ ID NO: 1, or a mammalian homologue thereof, nor has the specification demonstrated that the modulation of the expression of a nucleic acid encoding such polypeptide can be used to inhibit or treat any kidney, inflammatory, or cardiac disease, including viral myocarditis, cardiac hypertrophy, or myocardial

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infarction. The need for such research clearly indicates that the nucleic acid or the protein it encodes is not disclosed as to a currently available or substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. Further, a starting material does not have substantial utility when further experimentation must be conducted to determine the use for that starting material. The research contemplated by applicant(s) to characterize potential protein products, and determine therapeutic and diagnostic uses does not constitute a specific and substantial utility. Identifying and studying the properties of a nucleic acid or protein itself or the mechanisms in which such are involved does not define a "real world" context or use. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility of the utility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the nucleic acid and/or protein compound(s) such that another non-asserted utility would be well established for the compounds.

The specification teaches that a differentially expressed rat sequence, termed "P00188_D12" was identified by analysis of left ventricle tissue obtained from an in vivo model of ventral myocarditis (page 56). The specification asserts that the differentially expressed nucleic acids can be used as a diagnostic. This assertion has been thoroughly reviewed, however the teachings of the specification do not support how one of skill in the art would use the claimed nucleic acid as a diagnostic. Firstly, it is noted that the specification teaches that in vivo

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experimentation revealed that in the rat myocardial infarction model and the rat cardiac hypertrophy model, the gene corresponding to SEQ ID NO 2 was under expressed by about 1.8 fold and 2.5 fold, respectively. This expression pattern, however, does not appear to be diagnostic of cardiac diseases in general as the specification teaches that *in vivo*, the gene corresponding to SEQ ID NO 2 was over expressed in the mouse viral myocarditis model (See p. 65, lines 15-24). Furthermore, the specification fails to teach corroborative evidence for such *in vivo* expression patterns. The specification teaches that in *in vitro* experiments, rat cardiac myocytes were treated with various growth factors and cytokines known to induce cardiac hypertrophy (see p. 72, lines 7-9). However, while SEQ ID NO 2 was under expressed in the *in vivo* rat cardiac hypertrophy model, it was over expressed in cardiac myocytes cells where cardiac hypertrophy was induced (see p. 74, and figure 4). Therefore, given the results in the specification, the skilled artisan would not be able to identify any specific cardiac disease based on detection of either over expression or under expression of SEQ ID NO 2. Further experimentation would be required of the skilled artisan to reasonably confirm a real world context of use for the claimed nucleic acids.

At page 66, the specification teaches that the putative protein (SEQ ID NO: 1) encoded by SEQ ID NO: 2 contains a putative signal sequence and a "probable" transmembrane region. However, a large number of proteins with different functions contain both of these types of domains, such that the possession of these domains does not convey to the skilled artisan any specific or substantial utility for the claimed sequences. Additionally, the specification teaches that a BLAST search revealed "a good match" for SEQ ID NO: 2 with 3 different ESTs, however the specification does not teach the degree of homology present, nor the function of these ESTs.

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Additionally, even if the function were known, such evidence would not predictably establish the function of the polypeptide of SEQ ID NO: 1. Fetrow teaches (Fetrow et al., J. Mol. Biol., vol. 282, pp 703-711, 1998) that although function prediction by homology to previously characterized proteins is extremely successful and is fast, cheap and reliable, there are several problems that limit its potential utility, one of which is that sequence homology does not guarantee functional similarity (p 704, col. 1, 1st full paragraph). Fetrow teaches that "threading"(analysis using structure prediction tools) can identify topological cousins, that is , protein families such as the α/β barrels with similar structures, but dissimilar functions. Fetrow teaches using a three dimensional descriptor of the active site of a protein, termed "fuzzy functional form" (FFF) and argues that threading alone is not enough to provide the required information about function because it has been shown that pairs of proteins can have similar structures but unrelated functions (p. 706, col. 2, last para). Fetrow teaches that because such topological cousins exist, knowledge of the structure is not equivalent to identification of protein function. Skolnick (Skolnick and Fetrow, TIBTECH, January 2000, vol. 18, pp 34-39) teaches (p. 35, "Box 1") that a common protein characteristic that makes functional analysis based only on homology especially difficult is the tendency of proteins to be multifunctional. Skolnick teaches that for example, lactate dehydrogenase binds NAD, substrate, and zinc and performs a redox reaction and that each of these occurs at different functional sites that are in close proximity and the combination of all four sites creates the fully functional proteins. Skolnick also cites RecA which contains a DNA binding domain, a multimerization domain and additional sites that bind regulatory proteins. Skolnick also teaches that the serine threonine phosphatase superfamily is a prime example of the difficulties of using standard sequence analysis to

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recognize the multiple functions found in single proteins. Skolnick teaches that this large protein family is divided into a number of subfamilies, all of which contain an essential phosphatase active site. He teaches that subfamilies 1, 2A and 2b exhibit 40% or more sequence identity between them, however each of these subfamilies is apparently regulated differently by the cell and observation suggest that there are different functional sites at which regulation can occur. Skolnick teaches that because the sequence identity between subfamilies is so high, standard sequence similarity methods could easily misclassify new sequences as members of the wrong subfamily if the functional sites are not carefully considered.

As noted by *Brenner v. Manson*, 383 US 519, 535-536 (1996), "Congress intended that no patents be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use - testing... a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."

The response traverses the rejection. The response asserts that differential expression of the claimed sequence was reasonably correlated to three specific cardiac diseases, myocardial infarction, cardiac hypertrophy, and viral myocarditis. The response asserts that because the specification discloses a correlation among differential expression levels of SEQ ID NO 2 with a variety of diseases, the claims are supported by a specific utility. The response also asserts that the subject matter has a substantial utility because the claimed subject has is useful in diagnosing various cardiac disease states. These arguments have been thoroughly reviewed but were found unpersuasive. While the specification shows differential expression with regard to SEQ ID NO: 2 in different types of cardiac diseases, this expression pattern is not correlative with regard to cardiac diseases in general or even between the same cardiac disease state in in vivo vs in vitro

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models. Thus, the mere fact that SEQ ID NO: 2 shows differential expression in cardiac diseases, such is not considered substantial because cardiac diseases can involve a large number of diseases that are not necessarily related to each other, and it is unclear whether over or under expression of SEQ ID NO: 2 is associated with such. For example, the specification teaches that in *in vitro* experiments, rat cardiac myocytes were treated with various growth factors and cytokines known to induce cardiac hypertrophy (see p. 72, lines 7-9). However, while SEQ ID NO 2 was under expressed in the *in vivo* rat cardiac hypertrophy model, it was over expressed in cardiac myocytes cells where cardiac hypertrophy was induced (see p. 74, and figure 4). Therefore, the differential expression exhibited by the specification is unclear as to whether cardiac hypertrophy is correlated with under or over expression of SEQ ID NO: 2. The skilled artisan would have to perform further experimentation to determine how to use SEQ ID NO: 2 to diagnose cardiac hypertrophy. Further, although the *in vivo* cardiac models indicate that differential expression of SEQ ID NO: 2 could be associated with different cardiac disease states, the conflicting *in vitro* data presented by the specification, indicates that further experimentation must be conducted to determine if and how the differential expression of SEQ ID NO: 2 is correlated to different disease states. The rejection is maintained.

Claim Rejections - 35 USC § 112

5. Claims 3, and 5-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making an array comprising a nucleic acid molecule comprising 20-80 nucleotides of SEQ ID NO: 2 or encoding the protein of SEQ ID NO: 1 or the

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complement of the nucleic acid molecule, does not reasonably provide enablement for using such an array.

Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention, including an array comprising a nucleic acid molecule encoding the protein of SEQ ID NO: 1, or the complement of the nucleic acid molecule.

The specification teaches that a differentially expressed rat sequence, termed “P00188_D12” was identified by analysis of left ventricle tissue obtained from an *in vivo* model of ventral myocarditis (page 56). The specification asserts that the differentially expressed nucleic acids can be used as a diagnostic. This assertion has been thoroughly reviewed, however the teachings of the specification do not provide any guidance to the skilled artisan to make broadly “any” nucleic acid molecule complementary to any reference RNA or DNA encoding SEQ ID NO: 1, isolated from different types of samples set forth in claim 3 to be used as a diagnostic not do the teachings of the specification support how one of skill in the art would use the claimed nucleic acid as a diagnostic. Firstly, it is noted that the specification teaches that *in vivo* experimentation revealed that in the rat myocardial infarction model and the rat cardiac hypertrophy model, the gene corresponding to SEQ ID NO 2 was under expressed by about 1.8 fold and 2.5 fold, respectively. This expression pattern, however, does not appear to diagnostic of cardiac diseases in general as the specification teaches that *in vivo*, the gene corresponding to SEQ ID NO 2 was over expressed in the mouse viral myocarditis model (See p. 65, lines 15-24). Furthermore, the specification fails to teach corroborative evidence for such *in vivo* expression

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patterns. The specification teaches that in *in vitro* experiments, rat cardiac myocytes were treated with various growth factors and cytokines known to induce cardiac hypertrophy (see p. 72, lines 7-9). However, while SEQ ID NO 2 was under expressed in the *in vivo* rat cardiac hypertrophy model, it was over expressed in cardiac myocytes cells where cardiac hypertrophy was induced (see p. 74, and figure 4). Therefore, given the results in the specification, the skilled artisan would not be able to identify any specific cardiac disease based on detection of either over expression or under expression of SEQ ID NO 2. Further, the specification is silent as to any renal or inflammatory disease which may be associated with SEQ ID NO: 1 or 2.

Given the conflicting guidance in the specification regarding the very different expression patterns of nucleic acids encoding SEQ ID NO: 1 in different cardiac models, the skilled artisan would be required to perform a large amount of trial and error experimentation to arrive at a diagnostic for an array or kit as claimed as well as with regard to the extremely broad scope of diseases encompassed by the claims. Thus given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of that art, the large quantity of research required to define these unpredictable variables, the lack of guidance provided in the specification, and the conflicting teachings in the specification balanced only against the high skill level in the art, it is the position of the examiner that it would require undue experimentation for one of skill in the art to use the claimed invention.

The response traverses the rejection. The response asserts that the claimed subject matter functions as a diagnostic and serves the specific and substantial purpose of allowing a clinician to make an initial assessment regarding whether a patient is suffering from a cardiac disease such as infarction, hypertrophy, or viral myocarditis. This argument has been thoroughly reviewed

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but was found unpersuasive because given the conflicting evidence in the specification with regard to different expression levels with regard to SEQ ID NO: 2, not only between different cardiac disease, but also between in vivo and in vitro experiments with the same cardiac disease, a clinician would not be capable of determining whether a patient was suffering from cardiac hypertrophy or viral myocarditis or myocardial infarction solely based on the differential expression of SEQ ID NO: 2. Further, unpredictable experimentation, as evidenced by the conflicting data in the specification, would be required to determine how to use SEQ ID NO: 2 to diagnose cardiac hypertrophy, or viral myocarditis, or infarction. The unpredictability of the outcome of such experimentation is what renders it undue. The Mason et al reference has been thoroughly reviewed but was found unpersuasive as it does not contain any evidence or discussion as to how to use expression levels of SEQ ID NO: 2 to diagnose cardiac hypertrophy or viral myocarditis or myocardial infarction. The rejection is maintained.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 3, 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Accession number AI104132 (January 1999) in view of Schena (Schena et al; PNAS, vol. 93, pages 10614-10619, 1996).

Accession number AI104132 teaches an EST cDNA sequence from normalized rat heart. The accession number teaches an oligonucleotide which comprises 20-80 bases of SEQ ID NO: 2 (see alignment). The accession number does not teach an array comprising an oligonucleotide comprising 20-80 bases of SEQ ID NO: 2, however Schena teaches that microarrays containing cDNAs can be constructed to quantitatively monitor differential gene expression (see abstract). Schena teaches that parallel gene analysis with microarrays provides a rapid and efficient method for large scale gene discovery. Schena exemplifies the method with human cDNAs. With regard to claim 6, Schena teaches that the method of gene expression analysis involves a highly sensitive two color hybridization assay (detectable label; see abstract) as well as probes for hybridization (an oligonucleotide probe, PCR reagent [it is noted that a probe can also be used as a primer, and thus meets the structural requirements of a "PCR reagent"; see page 10614, col. 2, "Hybridization and Scanning"]). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to construct an array comprising the EST cDNA taught by Accession number AI104132 given the teachings of Schena. The ordinary artisan would have been motivated to construct an array comprising the EST cDNA taught by Accession number AI104132 because Schena teaches that arrays comprising cDNAs can be constructed to quantitatively monitor differential gene expression and that parallel gene analysis

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with microarrays provides a rapid and efficient method for large scale gene discovery. With regard to the "kits" in claims 5 and 6, it is noted that the recitation provides for no additional structural requirements to distinguish from the composition taught by Accession number AI104132 in view of Schena.

Conclusion

9. No claims are allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Jehanne Sitton
Primary Examiner
Art Unit 1634

7/23/07